

**Fishman LM, Anderson C, Rosner B. BOTOX and Physical Therapy in the Treatment of Piriformis Syndrome. Am J Phys Med Rehabil 2002;81:936-942.**

Design: Randomized clinical trial

Population/sample size/setting:

- 67 patients (21 men, 46 women, mean age 57) treated for piriformis syndrome at Columbia College in New York
- Eligible patients presented with buttock pain and sciatica and had at least a 1.86 ms delay in the posterior tibial H-reflexes on EMG when the affected thigh was placed in flexion, adduction, and internal rotation (FAIR)
  - o The delay was calculated by comparing the H-reflex in the anatomic position and in the FAIR position, and was chosen because 1.86 ms is three standard deviations above the mean H-reflex delay

Main outcome measures:

- All participants received piriformis injections under electrophysiologic guidance, followed by a twice-weekly physical therapy program
  - o PT included ultrasound, hot packs, manual stretching of the piriformis muscle, myofascial release at the lumbosacral paraspinal muscles, and McKenzie exercises
  - o PT was continued for 12 weeks, with follow-up exams every 2 weeks
- Randomization was to one of three injections: 200 U botulinum toxin type A (BTX, n=21), 20 mg triamcinolone and 1.5 ml of 2% lidocaine (n=31), or 2 ml of normal saline as placebo (n=15)
- Main outcome was the proportion of patients reporting a 50% reduction on pain VAS on each of the two final visits after the injection
  - o This outcome was achieved by 13 of 21 BTX patients (65%), 10 of 31 triamcinolone/lidocaine patients (32%), and 1 of 15 placebo patients (6%)
- The average age of the placebo group was greater (60.75) than for the BTX group (53.69) or the triamcinolone group (55.5)

Authors' conclusions:

- BTX was more effective in treating piriformis syndrome than either placebo or triamcinolone plus lidocaine
- Age may also be a factor, since the placebo group was older and the average age of the non-responders was also older than the responders to BTX

Comments:

- Description of randomization is sparse, but the fact that the code was read by the nurse loading the syringe is probably an acceptable indicator of concealment of allocation, and that that source of bias was controlled
- Baseline characteristics in Table 2 omit the baseline pain VAS
- The issue of age as a confounder could easily be resolved by logistic regression using age and treatment as independent variables and response as

the dependent variable; the treatment effect between BTX and placebo is too large to be very susceptible to age confounding

- It appears that there was attrition in the placebo group more than in the active injection groups
  - o Since patients who had less than two consecutive follow-up assessments were excluded from the analysis, this attrition may have been due to lack of effect of the saline injection; this should not be expected to bias the results of the analysis significantly
- Each of the three groups had more than 3 years of sciatica, making the study relevant to a chronic pain guideline

Assessment: Adequate for evidence that 100 U of BTX may effectively alleviate pain due to electromyographically proven piriformis syndrome